

**iPLEDGE PROGRAM  
FREQUENTLY ASKED QUESTIONS**

**A. TECHNICAL ASSISTANCE**

**B. PHARMACY**

**C. ALL USERS**

## **A. TECHNICAL**

### **What are the steps for first-time login to iPLEDGE?**

*Once registered, you will receive your username and password in the mail. Upon first login to iPLEDGE you will be asked to select a personal 4-digit numeric password and select a date of personal significance. The selection of a personal password is a security feature that ensures password confidentiality. A date of personal significance is collected by the system as confidential data that will be asked of you for identity authentication purposes should you require assistance from a Call Center operator during your participation in the iPLEDGE program. The date of personal significance can be any memorable date such as your birth date or wedding date.*

*If you are logging into iPLEDGE via phone or web for the first time you will enter your Username and Password from the user form that was mailed to you [Please see “**How can I login using my telephone?**” or “**How can I login using the web?**”]. Immediately after you have successfully logged in the system will ask you to select your personal password. You will be asked to enter the old (original) password from your user form and then you will enter a new 4-digit number of your choice. You will use the new password you have just chosen to login again in the future. To continue, you will be asked for your new password, then you will be asked to enter your date of personal significance twice. If you are using the telephone system you will enter the date in a mmddyyyy format. If you are using the iPLEDGE website you will enter the date in a mm/dd/yyyy format using the forward slash key. Upon successful entry of the date of personal significance the system will proceed to your main menu of options and you may begin performing functions in the iPLEDGE system.*

### **How can I login using the web? How do I handle Internet browser issues?**

*To use the iPLEDGE web functionalities it is required that you use Internet Explorer 6.0 or greater. If you do not have this Internet browser, you can download it at [www.microsoft.com](http://www.microsoft.com). To login to iPLEDGE go to [www.ipledgeprogram.com](http://www.ipledgeprogram.com) and locate the Login section in the middle of the screen. Type your username and password into the appropriate boxes. For example, if your username is ABC123, type exactly ABC123 in the Username box. If your password is 1234, type 1234 in the Password box. Click on the green “Login” button and your homepage with all appropriate functions will appear. If you are experiencing browser issues, your browser (i.e. Mozilla Firefox) may be blocking the iPLEDGE site. You can resolve this by 1) Disabling the pop-up blocker completely every time you need to use the site, or 2) adding [www.ipledgeprogram.com](http://www.ipledgeprogram.com) into your browser’s list of allowed sites. If this does not resolve the issue, it is recommended that you use Internet Explorer 6.0.*

### **What should I do if I become locked out of iPLEDGE?**

*If you make three unsuccessful attempts to login to iPLEDGE, a security feature that locks your account is deployed. Your account will automatically unlock after 30 minutes or you can speak with an iPLEDGE customer service representative to have it unlocked. Call the iPLEDGE Program at 1-866-495-0654 and listen for the option to speak to a representative.*

### **How can I login using my telephone?**

*To login using the telephone, dial 1-866-495-0654 and when you hear the main menu press 1 to login. The system first asks for your iPLEDGE user ID followed by the pound sign. Enter each digit of your user ID/username followed by the \* key on your telephone touchpad. Then press the # key at the end of your username. Refer to the table below.*

To Enter	Press	To Enter	Press	To Enter	Press	To Enter	Press
2	2*	A	22*	J	55*	S	77777*
3	3*	B	222*	K	555*	T	88*
4	4*	C	2222*	L	5555*	U	888*
5	5*	D	33*	M	66*	V	8888*
6	6*	E	333*	N	666*	W	99*
7	7*	F	3333*	O	6666*	X	999*
8	8*	G	44*	P	77*	Y	9999*
9	9*	H	444*	Q	777*	Z	99999*
0	0*	I	4444*	R	7777*	1	1*

*For example, if your username is 12345, type 1\*2\*3\*4\*5\*# on your telephone touchpad. If your username is alpha-numeric, for example BK12345, you would enter 222\*555\*1\*2\*3\*4\*5\*#. The system then asks for your iPLEDGE password. Enter your 4-digit numeric password. For example, if your password is 1234, simply enter 1234 (no \* or # this time). The system will confirm your successful login and will read your menu of options in the iPLEDGE system.*

### **How are iPLEDGE patient numbers assigned?**

*Once a Prescriber performs the “Activation” step in iPLEDGE, a shipment of patient educational kits is sent to the Prescriber’s address via UPS. The shipment includes two yellow kits (binders) for female patients of childbearing potential and two green kits (binders) for male patients or female patients who cannot get pregnant. Inside each kit is a tab labeled “Patient Identification Card”. In this section you will find a patient ID card attached, which can be peeled off and given to the patient along with the kit. In the upper right corner of the card appears a 10-digit patient number, which is the patient ID number you will enter when registering the patient. For each new patient you must have a new patient educational kit available to assign to the patient.*

### **How can I order additional program materials?**

*To order additional program materials prescribers must first login to iPLEDGE via telephone or web. If you are accessing the system by telephone you must login and then choose option 4, “To hear options on requesting program information.” The system will guide you through the ordering options. If you are accessing the system by web you must login and then click on “Order Materials” from the options listed down the left side of the screen. The system will display the options so you can place your order. The materials you order should be delivered to you within 7 to 10 business days from the order date.*

### **Why is the “Confirm Counseling” button not available for my patient on the web?**

*iPLEDGE enforces the requirements of the program, which include allowing only one prescription per patient per month. If your patient is not eligible for the next monthly visit according to the program timelines, the “Confirm Counseling” activity cannot be performed for that patient and the button will be grayed out. Once the appropriate number of days elapses from the previous counseling date, the system will allow you to enter the next counseling date.*

## **B. PHARMACY**

### **Please explain the registration process.**

*Registration and activation is a two-step process.*

Registration – A pharmacy may obtain a registration form on-line from the website's homepage or by calling 1-866-495-0654 and requesting to have a blank registration form faxed to the pharmacy. They are instructed to complete and fax the signed form to the iPLEDGE program 1-866-495-0660. If a pharmacy fills out the application form on-line they will still need to print it and fax or mail the signed form to iPLEDGE. The program requires a signed registration form received by iPLEDGE for each pharmacy that requests to enroll in the program.

Mailing – Once registered, your pharmacy will receive a mailing that includes your pharmacy's iPLEDGE Program username (which is your Pharmacy's NCPDP#), your pharmacy's iPLEDGE password, and instructions for pharmacy activation, among other iPLEDGE program related-materials.

Activation – You will need your username and password to activate. You may activate via either the website, [www.ipledgeprogram.com](http://www.ipledgeprogram.com), or automated phone system, 1-866-495-0654. For ease of use, it is recommended that you activate on the web site. The system will present a list of attestation points that you must agree to in order to complete your activation. This is a quick procedure that the Responsible Site Pharmacist can perform. If a store activates today, they will be included in tomorrow's Eligible Pharmacy list provided to the Wholesalers. A pharmacy must activate in order to be able to authorize a prescription in iPLEDGE. The activation expires in one year from the date of activation. A pharmacy only needs to activate once a year. There is no need to register every year.

### **How do I access the system if my password failed?**

*If the RSP knows his/her iPLEDGE username (NCPDP#) and date of personal significance, he/she can call the iPLEDGE Program at 1-866-495-0654 for assistance. The customer service representative will be able to reset the password and provide the new password via phone. This is a four digit temporary password. Immediately after you successfully login, the system will prompt you to change your password. If the RSP does not know his/her iPLEDGE username (NCPDP#) or date of personal significance, he/she can call the iPLEDGE Program for assistance at 1-866-495-0654. You will need to provide the NCPDP #, the RSP's name and license number. The customer service representative will be able to reset the password and provide the new password via phone. This is a four digit temporary password. Immediately after you successfully login, the system will prompt you to change your password.*

### **How does a pharmacy obtain drug from a wholesaler?**

*Pharmacies must be registered and activated in iPLEDGE in order to receive isotretinoin from a wholesaler. Wholesalers receive a daily list of pharmacies that are registered and activated in iPLEDGE. A pharmacy must be on this list in order to receive isotretinoin. The iPLEDGE Program will not accept faxes of registration forms, username and password forms, screen shots of activation pages, and the like as confirmation of eligibility to receive drug.*

### **Can representatives at the iPLEDGE Program confirm a pharmacy's activation status?**

*Yes, iPLEDGE representatives can confirm a pharmacy's activation status if the pharmacy has its NCPDP number and date of personal significance.*

**I have registered and activated in the iPLEDGE Program, however I am not listed with the wholesaler as an eligible pharmacy to receive drug.**

*One of the following scenarios could be your situation:*

- a) Updating the list of eligible pharmacies occurs once a day. If a pharmacy activates today, they will show up on tomorrow's list of eligible pharmacies. If your pharmacy was activated today (this includes cases where re-activation occurred due to an RSP change), your pharmacy will be able to order product the following day.*
- b) There may be a discrepancy with how your DEA number is listed on the Current Master.xls. Provide your NCPDP number to your wholesalers as the wholesalers can review their lists by both the pharmacy NCPDP number and DEA numbers. Your wholesaler should perform this query and if you still are not listed, your wholesaler can contact the iPLEDGE for further assistance.*
- c) For cases of DEA # discrepancies, you must have your DEA# corrected with NCPDP. You can do so by contacting Jeannine Deese at NCPDP at 480-477-1000 ext. 116. NCPDP updates the iPLEDGE Program weekly.*

**Have the specific 852 and 867 requirements been determined?**

*Contact Dave Flood at ValueCentric: 716-667-0297 Ext. 103, [dave.flood@valuecentric.com](mailto:dave.flood@valuecentric.com)*

**How do I change my responsible site pharmacist (RSP)?**

*The pharmacy can change its designated RSP at any time. The new RSP or the former RSP can make the change on the automated phone line at 1-866-495-0654 by following the appropriate prompts. Please see instructions below:*

### **Process to Change RSP**

Please follow this process to request a change in a pharmacy's Responsible Site Pharmacist (RSP).

**IMPORTANT:** Changing a pharmacy's RSP requires re-activation of the pharmacy to affirm that the new RSP will comply with iPLEDGE requirements.

Before you call iPLEDGE to request the change, please ensure that you have the following information available.

- 1. Pharmacy's username (NCPDP#)**
- 2. Pharmacy's Date of Personal Significance (DOPS).** If you do not know your pharmacy's DOPS, please reset it before calling iPLEDGE. Please refer to the section below for directions on how to reset a DOPS.
- 3. New RSP Name**
- 4. New RSP License #**

#### **Resetting a Pharmacy's Date of Personal Significance**

On the Web

1. Go to [www.ipleddgeprogram.com](http://www.ipleddgeprogram.com)
2. Log in using your username (NCPDP#) and password.
3. Select "Update Personal Details" on the left side of the screen
4. Select "Change Date of Personal Significance"
5. Enter requested data and select "Save Changes"
6. Write down the new Date of Personal Significance

#### On the Phone

1. Call 1-866-495-0654
2. Press 1 to continue in English
3. Select the option to login, then enter your username (NCPDP#) and password when prompted
4. Select the option to change personal information
5. Select the option to change your Date of Personal Significance
6. Enter requested information when prompted
7. Write down the new Date of Personal Significance

#### Changing the RSP

1. Call 1-866-495-0654
2. Press 1 to continue in English
3. Press #0 to transfer to the call center, then press 1 at the prompt
4. Press 2 for pharmacies.
5. A call center agent will answer the call. Tell them that you want to change your pharmacy's RSP and that you need to be transferred to the technical help desk.
6. A technical help desk agent will answer the transferred call. Tell the agent that you would like to change your pharmacy's RSP.
7. The agent will ask for your username (NCPDP#) and DOPS. This is used for authentication. Once authenticated, the agent will ask for the new RSP's name and license #.
8. Once the change is complete, you may ask the agent to transfer you back into the phone system to re-activate the pharmacy or you may perform this on the website. The website is faster and easier.

#### To Activate / Re-activate a Pharmacy

##### On the Web

1. Go to [www.ipledgeprogram.com](http://www.ipledgeprogram.com)
2. Log in using your username (NCPDP#) and password.
3. Select "ACTIVATE PHARMACY REGISTRATION" on the left side of the screen or the green "Activate" button in the middle of the screen.
4. Read the attestation points listed on the screen
5. Select "I attest to the statements above"
6. Select "Submit"

##### On the Phone

1. Call 1-866-495-0654 (skip this step if you were transferred back into the phone system)
2. Press 1 to continue in English
3. Select the option to log in, then enter your username (NCPDP#) and password when prompted
4. Select the option to activate your pharmacy
5. Press 1 to continue
6. Follow the prompts

**IMPORTANT:** Failure to reactivate a pharmacy before midnight of the day the RSP was changed will cause the pharmacy to be removed from the Pharmacy Eligibility File that is sent to wholesalers and distribution centers. If this happens, the pharmacy will be added back to the list upon reactivation.

**How do I process a prescription that is more than 120 capsules per month?**

*A pharmacist may authorize more isotretinoin capsules than available in the provided drop down menu (120 max), by repeating the authorization process for the remainder of capsules necessary. The pharmacist should enter the patient's username and date of birth a second time and then check the box that states, "Please check this box to confirm that this is an additional fill for the same prescription." The pharmacist will then enter the NDC code, number of days dispensed, and the remaining capsules to authorize the remainder of the prescription. The pharmacist also can authorize a prescription requiring capsules with different NDC codes by repeating the authorization process for each unique NDC code. The pharmacist should complete all authorizations necessary for one prescription consecutively and without interruption. However, if interrupted the only requirement is that additional prescriptions must be authorized within one hour of the first prescription. In doing so, the pharmacist must check the box indicating that this is an additional fill for the same prescription. (Within that hour the pharmacist may log out and may authorize prescriptions for other patients.)*

**I have questions about a letter I received in the mail regarding the iPLEDGE Chain Pharmacy Agreement to Release Data.**

*If you have questions about this letter, please contact ValueCentric at 716-667-0297 x160*

**Can we still provide isotretinoin to patients on existing risk management programs (using the yellow stickers)?**

*The existing risk management programs for distributing, prescribing, and dispensing all isotretinoin drug products (S.M.A.R.T., A.L.E.R.T., S.P.I.R.I.T., and I.M.P.A.R.T.), including the use of the yellow adhesive qualification sticker on the written prescription for isotretinoin, will continue through February 28, 2006. Starting March 1, 2006, all prescriptions for isotretinoin must be authorized through the iPLEDGE program.*

**I have questions regarding product returns.**

*Please contact the appropriate manufacturers' vendors listed below:*

*Accutane (Roche): 1-800-526-0625*

*Amnesteem (Mylan): Stericycle at 1-800-796-9526*

*Claravis (Barr): Carolina Logistics at 1-800-967-5952*

*Sotret (Ranbaxy): Carolina Logistics at 1-817-868-5300*

**C. ALL USERS**

**If a patient's 7-day prescription authorization window expires before they arrive at the pharmacy to fill the prescription, is there any way to override the system?**

*No. A lapse in treatment would result when a registered patient does not pick up the isotretinoin prescription within seven days after the office visit, the office visit being day 1. This may result in a patient missing isotretinoin treatment for no less than 23 days. Patients should make every effort possible to complete the iPLEDGE program requirements and pick up the prescription within the 7-day window to avoid a lapse in isotretinoin treatment.*

**Is there a test database available for prescribers / staff / pharmacist / or patients to use for training purposes to get familiar with the iPLEDGE site?**

*At this time, there is no test database. Please refrain from entering dummy data in the iPLEDGE system as that could negatively impact patient data that is reported to the FDA.*

**How can I download iPLEDGE materials?**

*Users can download the iPLEDGE materials from the website using version Acrobat 7.0. The link to this free Acrobat download is available on any page that has materials available for download.*

**Can patients who do not reside in the U.S. but receive treatment and fill prescriptions in the U.S. participate in the iPLEDGE Program?**

*Residency is not a requirement of the program as long as patients see a doctor in the U.S. and fill their prescription in the U.S. However, a U.S. mailing address must be provided.*

**Will the manufacturers reinstate veterinary use of isotretinoin?**

*Isotretinoin is for human consumption only. At this time, there are no plans to include animals in the iPLEDGE program.*

**Can inpatient pharmacies obtain isotretinoin in the inpatient hospital setting?**

*Hospital pharmacies must follow all the requirements of the iPLEDGE program and cannot process partial isotretinoin prescriptions (or break blister packs). All pharmacies need to dispense a 30-day supply of isotretinoin because the iPLEDGE system will allow one prescription authorization a month.*